

Atty. Docket: 2884 (203-3592 PCT US)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

APPELLANTS: Bruce Jankowski, *et al.* **EXAMINER:** Gloria R. Weeks
SERIAL NO.: 10/540,197 **GROUP:** 3721
FILED: June 20, 2005 **DATED:** May 20, 2009
FOR: **VACUUM ASSISTED SURGICAL STAPLER**

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SUBSTITUTE APPEAL BRIEF

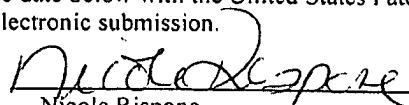
Dear Sir:

This Substitute Appeal Brief concerns an appeal from the Notice of Panel Decision from Pre-Appeal Brief Review (hereinafter "the Notice") that was mailed on March 4, 2009, and is being submitted in response to a Notification of Non-Compliant Appeal Brief that was mailed on May 5, 2009. The Notice was received in Response to a Pre-Appeal Brief Request for Review that was filed on January 20, 2009 in response to the Final Office Action that was mailed on September 11, 2008 (hereinafter "the Final Office Action") and the Advisory Action that was mailed on December 5, 2008 (hereinafter "the Advisory Action") in connection with the above-identified patent application.

CERTIFICATE OF TRANSMISSION UNDER 37 C.F.R. §1.8(a)

I hereby certify that this correspondence is being transmitted on the date below with the United States Patent and Trademark Office, PO Box 1450, Alexandria, VA 22313-1450, via electronic submission.

Dated: May 20, 2009


Nicole Rispone

I. REAL PARTY IN INTEREST

The real party in interest for this application is Tyco Healthcare Group LP (d/b/a Covidien), having a principal office at 60 Middletown Avenue, North Haven, CT 06473.

II. RELATED APPEALS AND INTERFERENCES

There are no other prior or pending appeals or interferences related to the above-identified application.

III. STATUS OF CLAIMS

The status of the claims in the above-identified application is as follows:

- A) Claims 6-12 and 19-28 are pending;
- B) Claims 6, 7, 19, 20, and 26 stand rejected and are being appealed; and
- C) Claims 8-12, 21-25, 27, and 28 stand objected to.

IV. STATUS OF AMENDMENTS

An Amendment was filed on November 12, 2008 in response to the Final Office Action. In the Amendment, Appellants presented arguments highlighting the patentably distinct features of the subject matter recited in Claims 6-12 and 19-28, and in view of those arguments, Appellants requested reconsideration of the above-identified application. In the Advisory Action, the Examiner indicated that Appellants arguments were considered, but that they were unpersuasive.

V. SUMMARY OF CLAIMED SUBJECT MATTER

The subject matter of the above-identified application relates to “surgical instruments, e.g., surgical fastener or stapler apparatus and, more particularly to circular surgical staplers for performing surgical procedures, including but not limited to rectal mucosectomies, rectal anapexies, anastamoses, hemorrhoidectomies, or the like” as well as “methods of performing such surgical procedures.” (Page 1, lines 4-8).¹

The surgical stapling apparatus and vacuum system recited in independent Claim 6 includes a surgical stapling apparatus 100 with a body portion 104, a shell assembly 107, and an anvil 108, as well as a vacuum device. (*See* page 6, lines 6-9; *see* page 10, lines 2-7; *see* FIG. 1)

The shell assembly 107 is positioned on a distal end of the body portion 104, (*see* page 10, lines 5-6; *see* FIG. 1), and includes an annular array of staples and at least one aperture 116. (*See* page 10, lines 5, 11, 12, 16, 17; *see* FIGS. 1, 2, 9). The anvil 108 is movably supported in relation to the shell assembly 107 for movement between spaced and approximated positions. (*See* page 10, lines 7-9; *see* page 11, lines 5-11).

The vacuum device includes a housing 140 and a vacuum conduit 144. (*See* page 11, lines 16-19; *see* FIGS. 2, 2A). The housing 140 is positioned about at least a portion of the shell assembly 107 of the surgical stapling apparatus 100 to define a vacuum chamber 150, 182. (*See* page 12, lines 3-10; *see* page 14, line 17-18; *see* FIGS. 2, 7). The at least one aperture 116 of the shell assembly 107 is positioned within the vacuum chamber 150, 182, and the vacuum conduit 144 communicates with the vacuum chamber 150, 182. (*See* page 11, lines 19-21; *see* page 12, lines 3-6; *see* page 14, lines 18-21; *see* FIGS. 2, 2A, 7). The vacuum device further includes at least one vacuum tube 200 having a first end 200a that is positioned within the vacuum chamber

¹ Citations pertaining to disclosure in the above-identified application references the application as originally filed.

150, 182, and a second end 200b that is positioned within the inner chamber 150 of the shell assembly 107. (*See* page 15, lines 12-17; *see* page 16, lines 6-10; *see* FIGS. 8-11).

VI. GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL

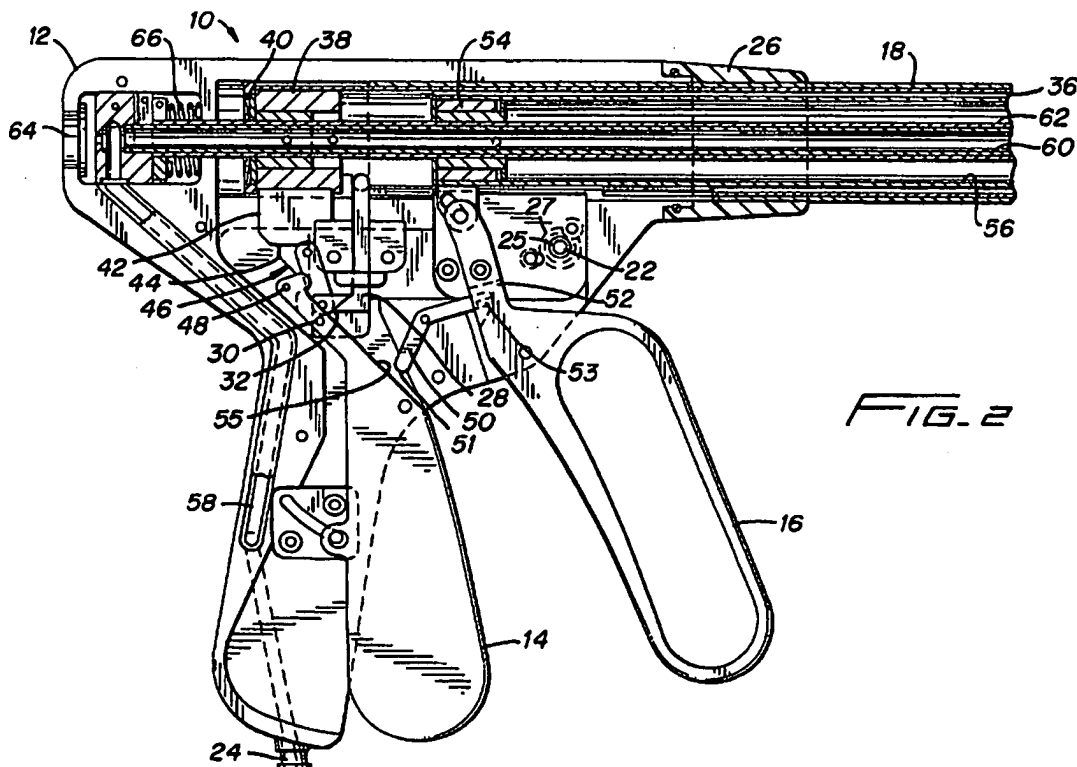
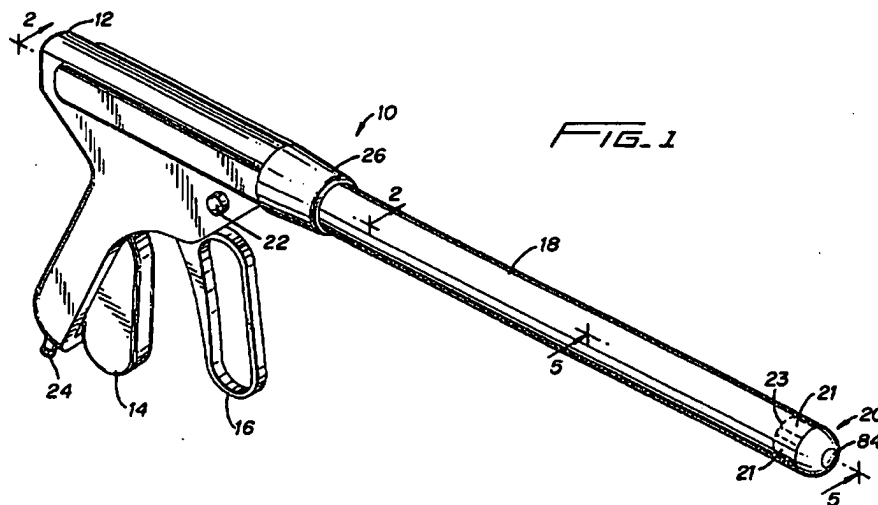
Appellants request review of the following grounds of rejection:

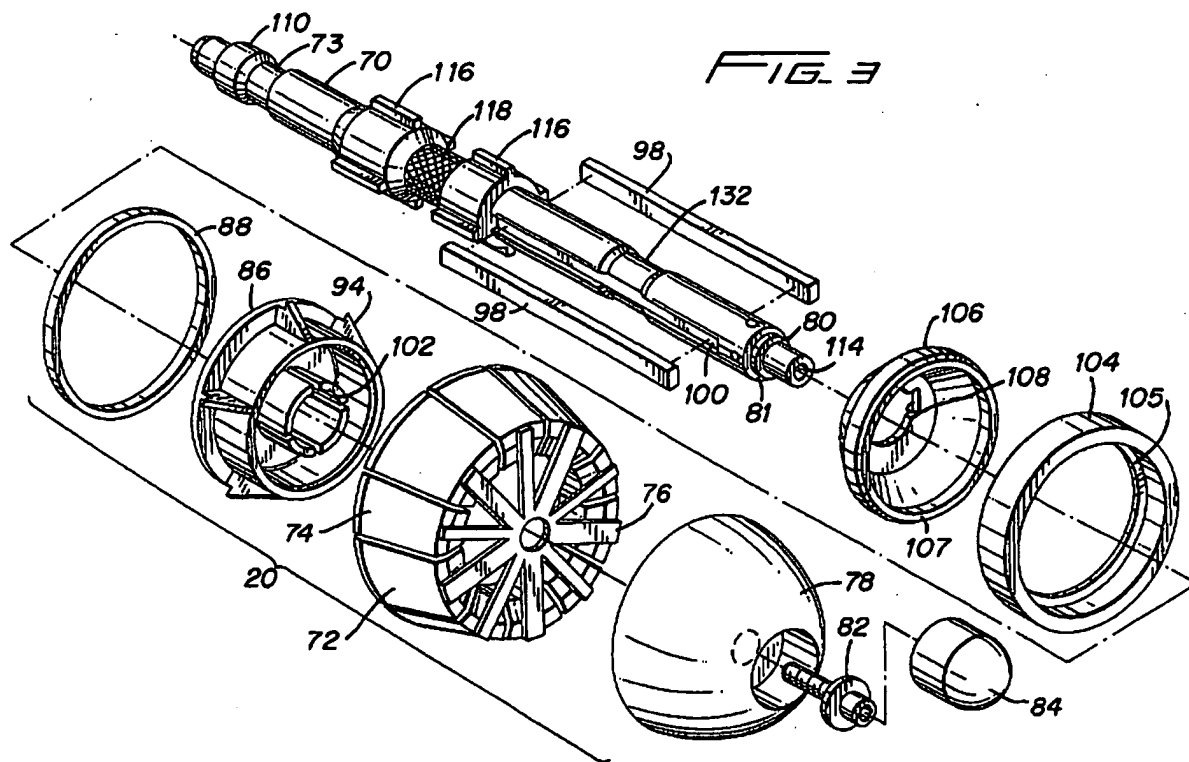
- A) The rejection of Claims 6, 19, 20, and 26 under 35 U.S.C. §102(b) as being anticipated by U.S. Patent No. 5,839,639 to Sauer, *et al.* (hereinafter “Sauer”); and
- B) The rejection of Claim 7 under 35 U.S.C. §103(a) as being unpatentable over Sauer.

VII. ARGUMENT

Sauer relates to “a surgical stapler apparatus.” (Col. 1, line 5). More particularly, Sauer relates to “a stapler anvil assembly for an end-to-end anastomosis stapler apparatus.” (Col. 1, lines 6-7). In one embodiment of the disclosure, Sauer discusses a collapsible anvil assembly 20 and an applicator instrument 10. (*See* col. 4, lines 18-19; *see* FIG. 1 below). The instrument 10 includes a handle housing 12 and an outer tube 18, (*see* col. 4, lines 20-22; *see* FIG. 1 below), and the anvil assembly 20 includes a plurality of anvil segments 21, which alternate between large segments 72 and small segments 74, as well as an anvil shaft 70. (*See* col. 4, lines 49-52; *see* FIG. 3 below). “Vacuum holes 112 are provided radially at a distal end of anvil shaft 70 and are communicable with a central bore 114 of anvil shaft 70.” (Col. 7, lines 52-54; *see* FIG. 3 below). The applicator instrument 10 further includes a vacuum passage 58 that extends between a vacuum connection port 24 and an air delivery tube 60 located axially within the instrument 10. (*See* col. 7, lines 25-33; *see* FIG. 2 below). The air delivery tube 60 serves to

provide a source of vacuum or suction to the collapsible anvil assembly 20, which draws tissue against the anvil segments 21 and between a snap cap pocket 104 and a snap cap 106. (See col. 4, lines 38-42; see col. 7, lines 39-52; see FIGS. 2, 3 below). The applicator 10 is then disengaged from the anvil assembly 20 such that an instrument (FIG. 16) can be attached to the anvil assembly 20. (See col. 10, lines 30-48).





In describing Sauer in the Final Office Action, the Examiner stated the following:

In reference to claims 6, 19, 20 and 26, Sauer et al. discloses a surgical stapling apparatus and vacuum system comprising: a shell assembly 18 positioned on a distal end and proximal end of a body portion 26; a movable anvil 20; an array of staples 23; an aperture 62; an annular knife (column 7 lines 43-46); a hollow vacuum housing sleeve 12 positioned about a proximal end of the shell assembly 18 to define a vacuum chamber and the distal end of the body 26, wherein the at least one aperture 60 is positioned within the vacuum chamber (figure 2); a vacuum conduit 58 communicating with the vacuum chamber; and at least one vacuum tube 60, 70 having a first end 60 positioned within the vacuum chamber and a second end 70 positioned within an inner chamber of the shell assembly 18. (Final Office Action, page 2) (emphasis added).

This position was maintained in the Advisory Action, where the Examiner stated that "element 12 of Sauer is found to meet the limitation of a vacuum chamber that receives an end of

vacuum tube 60 and an end of vacuum conduit 58 (figure 2), such that *vacuum tube 60* is positioned within an inner chamber of shell assembly 18.” (Advisory Action, page 2) (emphasis added).

Appellants respectfully submit that one skilled in the art would not interpret Sauer as suggested by the Examiner in the Final Office Action and the Advisory Action. Specifically, Appellants maintain that the Sauer fails to disclose each and every element recited in Claims 6, 19, 20, and 26, and that Sauer fails to render obvious the subject matter recited in Claim 7 as a whole. Accordingly, Appellants maintain that Claims 6, 19, 20, and 26 are allowable over Sauer under 35 U.S.C. §102(b), and that Claim 7 is allowable over Sauer under 35 U.S.C. §103(a).

- a) **Claims 6, 19, 20, and 26 are allowable over Sauer under 35 U.S.C. §102(b), as Sauer fails to disclose each and every element recited in Claims 6, 19, 20, and 26.**

The Examiner’s characterization of Sauer offered in the Final Office Action and the Advisory Action relies upon Sauer’s handle housing 12 for disclosure of both the “housing” of the “vacuum device” and the “vacuum chamber” recited in independent claim 6. Appellants respectfully submit, however, that a single element of Sauer cannot properly be relied upon for the disclosure of two separate and distinct elements of the “surgical stapling apparatus and vacuum system” recited in the claims. This is particularly true when the recited elements differ greatly in structure and function. Specifically, the recited “housing” constitutes a component of the structure effectuating the creation of a vacuum, whereas the recited “vacuum chamber” provides an internal space that can be depressurized upon the connection of a vacuum source. (See, e.g., page 11, line 16 – page 12, line 10.) Accordingly, and without acknowledging the accuracy or propriety of the Examiner’s analogies, Appellants respectfully submit that Sauer is either devoid of the recited “housing” of the “vacuum device” or the recited “vacuum chamber.”

In either scenario, Appellants respectfully submit that the Examiner's rejection fails to establish a *prima facie* case of anticipation under 35 U.S.C. §102(b).

Moreover, Appellants draw attention to the fact that "housing" of the "vacuum device" is recited as at least partially defining the recited "vacuum chamber." Given the Examiner's characterization of Sauer's handle housing 12 as both the recited "housing" of the "vacuum device" and the "vacuum chamber," upholding the Examiner's rejection would be tantamount to an endorsement of the statement that Sauer's handle housing 12 defines the handle housing 12.

Additionally, the Examiner's characterization of Sauer relies upon the air delivery tube 60 for disclosure of both the "at least one aperture" included in the "shell assembly" and the "at least one vacuum tube" recited in independent claim 6. Again, the Examiner relies upon a single element of Sauer, i.e., the air delivery tube 60, for the disclosure of two separate and distinct elements of the "surgical stapling apparatus and vacuum system" recited in the claims. Accordingly, and without acknowledging the accuracy or propriety of the Examiner's analogies, Appellants respectfully submit that Sauer is also devoid of either the recited "at least one aperture" included in the "shell assembly" or the "at least one vacuum tube," and therefore, that the Examiner's rejection fails to establish a *prima facie* case of anticipation under 35 U.S.C. §102(b).

In view of these deficiencies in the Examiner's argument, Appellants respectfully submit that the rejection of Claims 6, 19, 20, and 26 under 35 U.S.C. §102(b) is legally insufficient, and therefore, that the rejection cannot be properly maintained.

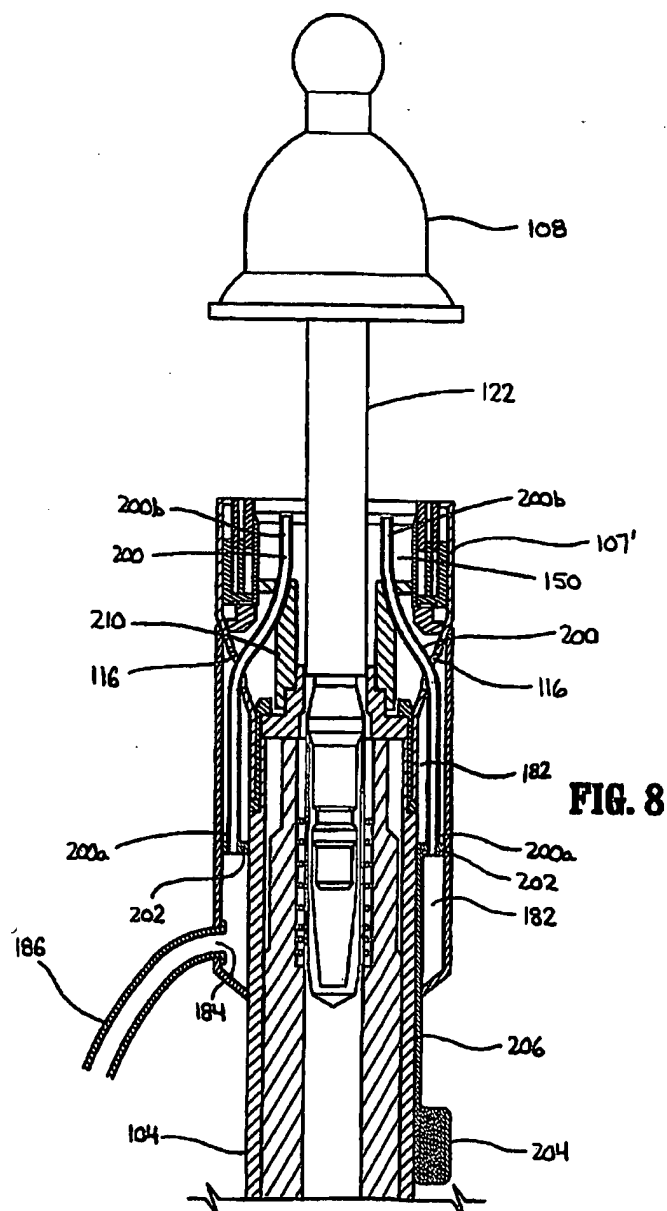
Furthermore, Appellants draw attention to the disclosure in Sauer stating that the “vacuum passage 58 . . . extends between the vacuum connection port 24” and that the “air delivery tube 60,” which “provide[s] a source of vacuum or suction to the collapsible anvil assembly 20,” (col. 7, lines 28-33), and that once a source of vacuum is connected to the vacuum connection 24 and turned on, “it creates a source of vacuum through vacuum passage 58 and thus through air delivery tube 60.” (Col. 9, lines 63-64). Thus, the created vacuum extends from the source to the anvil assembly 20 through the vacuum passage 58 and the air delivery tube 60. None of these components, neither the vacuum passage 58 nor the air delivery tube 60, includes any perforations, apertures, or other structure that would increase the size of the space being depressurized. Accordingly, Appellants respectfully submit that proximally of the anvil assembly 20, the vacuum exists solely within the confines of the vacuum passage 58 and the air delivery tube 60, and as such, that the only structure in Sauer possibly comparable to the recited “vacuum chamber” lies within and between the vacuum connection port 24, the vacuum passage 58, and the air delivery tube 60. However, as can clearly be appreciated through reference to FIG. 2 of Sauer above, this structure is not defined between the handle housing 12 and the outer tube 18, which were respectively characterized by the Examiner as the “housing” of the “vacuum device” and the “shell assembly” recited in the claims. Therefore, Appellants respectfully submit that Sauer fails to disclose, or even suggest, “a vacuum device including a housing . . . positioned about at least a portion of the shell assembly of the surgical stapling apparatus to define a vacuum chamber,” as recited in independent Claim 6. In contrast, Sauer’s instrument merely includes an anvil shaft 70 having a central bore 114 and vacuum holes 112 that radiate outwardly from therefrom.

Additionally, as indicated in an Amendment that was submitted on November 12, 2008 in response to the Final Office Action, Appellants respectfully disagree with the characterization attributed to particular elements of Sauer's apparatus.

The structure identified by the Examiner as the recited "shell assembly" actually constitutes the outer tube of the applicator 10, and the structure identified by the Examiner as the recited "array of staples" actually constitutes a cartridge housing that maintains the collapsible anvil assembly 20 within a distal end of the outer tube 18. Additionally, the structure characterized by the Examiner as the "hollow vacuum sleeve," which is identified by the reference character 12 (FIGS. 1, 2 above), actually constitutes the handle housing, which is spaced from the anvil assembly 20 by the length of the outer tube 18, and is therefore not "positioned about at least a portion of the shell assembly of the surgical stapling apparatus to define a vacuum chamber," as recited in independent Claim 6.

Further, Appellants respectfully disagree with the Examiner's argument that Sauer discloses "at least one vacuum tube 60, 70 having a first end 60 positioned within the vacuum chamber and a second end positioned within an inner chamber of the shell assembly 18." (Final Office Action, page 2). As clearly shown in FIG. 2 of Sauer above, the proximal end of air delivery tube 60 extends into the handle housing 12, and the distal end of the anvil shaft 70 is secured to the anvil assembly 20. Neither the air delivery tube 60 nor the anvil shaft 70 includes an end that is positioned within any structure than can reasonably be construed as a "vacuum chamber" or "an inner chamber of the shell assembly" in light of the disclosure offered in Sauer's written description. Accordingly, Appellants respectfully submit that Sauer fails to disclose "at least one vacuum tube having a first end positioned within a vacuum chamber and a second end positioned within an inner chamber of the shell assembly," as recited

in independent Claim 6. To further highlight the patentable differences between the structure of Sauer and the subject matter recited in independent Claim 6, Appellants draw the Examiner's attention to FIG. 8 of the present application, which has been reproduced below. FIG. 8 illustrates a vacuum tube 200 having a first end 200a that is positioned within the vacuum chamber 150, 182, and a second end 200b that is positioned within the inner chamber 150 of the shell assembly 107. (See page 15, lines 12-17; see page 16, lines 6-10).



For at least these reasons, *inter alia*, Appellants respectfully submit that Sauer fails to disclose each and every element recited in independent Claim 6, and therefore, that independent Claim 6 is allowable over Sauer under 35 U.S.C. §102(b). Since Claims 19, 20, and 26 depend either directly or indirectly from independent Claim 6, and include each element recited therein, for at least the reasons that independent Claim 6 is allowable over Sauer under 35 U.S.C. §102(b), *inter alia*, Appellants respectfully submit that Claims 19, 20, and 26 are also allowable over Sauer under 35 U.S.C. §102(b).

b) Claim 7 is allowable over Sauer under 35 U.S.C. §103(a) as Sauer fails to suggest the subject matter of Claim 7 as a whole.

In the Final Office Action, the Examiner acknowledged that Sauer fails to disclose an apparatus including a plurality of vacuum tubes, as substantially recited in Claim 7, but argued that it would have been obvious to one of ordinary skill in the art at the time of the invention to modify Sauer to include a second vacuum tube. (See Final Office Action, page 3).

Assuming, *arguendo*, that incorporating additional vacuum tubes into the Sauer apparatus would have been obvious to one of ordinary skill in the art, incorporating these additional tubes would fail to cure the aforescribed deficiencies in Sauer.

For at least this reason, *inter alia*, Appellants respectfully submit that Sauer fails to suggest the subject matter of independent Claim 6 as a whole, and therefore, that independent Claim 6 is allowable over Sauer under 35 U.S.C. §103(a). Since Claim 7 depends directly from independent Claim 6, and includes each element recited therein, for at least the reasons that independent Claim 6 is allowable over Sauer under 35 U.S.C. §103(a), *inter alia*, Appellants respectfully submit that Claim 7 is also allowable over Sauer under 35 U.S.C. §103(a).

CONCLUSION

In view of the foregoing remarks and arguments, Appellants respectfully submit that the rejections of Claims 6, 19, 20, and 26 under 35 U.S.C. §102(b) as being anticipated by Sauer, and Claim 7 under 35 U.S.C. §103(a) as being unpatentable over Sauer, have been traversed.

Please charge any deficiency, as well as any other fee(s) which may become due under 37 C.F.R. §1.16 and/or 1.17 at any time during the pendency of this application, or credit any overpayment of such fee(s), to Deposit Account No. **21-0550**. Also, in the event any extensions of time for responding are required for the pending application(s), please treat this paper as a petition to extend the time as required, and charge Deposit Account No. **21-0550** therefor.

Respectfully submitted,



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VIII. APPENDIX OF CLAIMS

Claims 1-5 (canceled).

Claim 6 (rejected): A surgical stapling apparatus and vacuum system, the system comprising:

a surgical stapling apparatus including a body portion, a shell assembly and an anvil, the shell assembly being positioned on a distal end of the body portion and including an annular array of staples and at least one aperture, the anvil being movably supported in relation to the shell assembly between spaced and approximated positions; and

a vacuum device including a housing and a vacuum conduit, the housing being positioned about at least a portion of the shell assembly of the surgical stapling apparatus to define a vacuum chamber, the at least one aperture being positioned within the vacuum chamber, the vacuum conduit communicating with the vacuum chamber, and at least one vacuum tube having a first end positioned within the vacuum chamber and a second end positioned within an inner chamber of the shell assembly.

Claim 7 (rejected): A system as recited in Claim 6, wherein the at least one vacuum tube includes a plurality of vacuum tubes.

Claim 8 (objected to): A system as recited in Claim 7, further including a manifold slidably positioned within the vacuum chamber, the first end of each of the vacuum tubes being secured to the manifold.

Claim 9 (objected to): A system as recited in Claim 8, further including an actuator operably connected to the manifold, the actuator being movable to move the manifold and the plurality of vacuum tubes between a non-deployed position in which the second end of each of the vacuum tubes is positioned within the shell assembly and a deployed position in which the second end of each of the vacuum tubes is positioned externally of the shell assembly.

Claim 10 (objected to): A system as recited in Claim 9, wherein at least one of the vacuum tubes is formed of a shape-memory material.

Claim 11 (objected to): A system as recited in Claim 10, wherein the second end of the at least one of the plurality of vacuum tubes points radially outwardly of the shell assembly in the deployed position.

Claim 12 (objected to): A system as recited in Claim 10, wherein the second end of the at least one of the plurality of vacuum tubes is positioned radially outwardly of the shell assembly in the deployed position.

Claims 13-18 (canceled).

Claim 19 (rejected): A system as recited in Claim 6, wherein the housing defines a hollow sleeve.

Claim 20 (rejected): A system as recited in Claim 19, wherein the hollow sleeve is positioned about the distal end of the body portion and a proximal end of the shell assembly.

Claim 21 (objected to): A system as recited in Claim 20, wherein the proximal end of the shell assembly includes a conical portion, the at least one aperture being formed in the conical portion.

Claim 22 (objected to): A system as recited in Claim 21, wherein the at least one aperture includes a plurality of apertures.

Claim 23 (objected to): A system as recited in Claim 9, wherein the actuator includes a finger actuator which is connected to the manifold by a link.

Claim 24 (objected to): A system as recited in Claim 23, wherein the finger actuator, the link and the manifold are integrally formed.

Claim 25 (objected to): A system as recited in Claim 23, wherein the finger actuator is slidably positioned along an outer surface of the body portion.

Claim 26 (rejected): A system as recited in Claim 6, further including an annular knife blade positioned about the inner chamber of the shell assembly.

Claim 27 (objected to): A system as recited in Claim 9, further including guide structure configured to guide movement of the plurality of vacuum tubes between the non-deployed position and the deployed position.

Claim 28 (objected to): A system as recited in Claim 27, wherein the guide structure is supported within the inner chamber of the shell assembly.

IX. EVIDENCE APPENDIX

None

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X. RELATED PROCEEDINGS APPENDIX

None